K120233

MAR - 9 2012

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Name, Address, Phone and Fax number of the Applicant

Accuray Incorporated
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Contact Person

Anne Schlagenhaft

Date Prepared

December 6, 2011

Device Name

Trade Name: Synchrony Respiratory Tracking System, an option to the CyberKnife® Robotic Radiosurgery System and CyberKnife VSI™ Robotic Radiosurgery System
Classification Name: Medical charged particle radiotherapy device

Device Description

Irradiation of lesions that move during breathing, such as those located in the lung or near the diaphragm, are typically performed during patient breath-holds. The Synchrony Tracking System option to the CyberKnife System is designed to treat lesions while they are moving during the respiratory cycle. This offers the ability to reduce normal tissue exposure by using smaller irradiation margins, shorten treatment times, increase accuracy and provide more comfort for the patient.

During respiratory tracking, a correspondence between surface (e.g., thorax/abdomen) movement and movement of the target lesion is developed prior to the start of treatment and is regularly updated during treatment each time the CyberKnife System acquires a new pair of x-ray images. This correspondence is then used to estimate lesion position in real time by monitoring surface movement during treatment.

The Synchrony Tracking System provides the CyberKnife System with the capability to monitor the patient's respiration and command the robot manipulator to compensate for the treatment target motion within the body, in real-time, while the radiation is being delivered.

The Synchrony Respiratory Tracking System includes a sensor assembly, tracking targets, electronics to translate signals, and a controller.

Intended Use

The Synchrony® Respiratory Tracking System is an option to the CyberKnife® Robotic Radiosurgery System and CyberKnife VSI™ Robotic Radiosurgery System and is intended to enable dynamic image-guided stereotactic radiosurgery and precision radiotherapy of lesions, tumors and conditions that move under the influence of respiration.

Substantial Equivalence

The Synchrony® Respiratory Tracking System is substantially equivalent to the predicate device. The intended use, principles of operation, technological characteristics and labeling are the same or equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR - 9 2012

Ms. Anne Schlagenhaft
Senior Regulatory Affairs Specialist
Accuray Incorporated
1310 Chesapeake Terrace
SUNNYVALE CA 94089

Re: K120233
Trade/Device Name: Synchrony® Respiratory Tracking System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 20, 2012
Received: January 25, 2012

Dear Ms. Schlagenhaft:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: Synchrony® Respiratory Tracking System

Indications for Use:

The Synchrony® Respiratory Tracking System provides an option to the CyberKnife Robotic Radiosurgery System and CyberKnife VSI Robotic Radiosurgery System that enables dynamic image-guided stereotactic radiosurgery and precision radiotherapy of lesions, tumors and conditions that move under the influence of respiration.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120233